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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,487	04/04/2001	Edward I. Wulfman	89000.3007	3007

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EXAMINER

ODLAND, KATHRYN P

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,487

Applicant(s)

WULFMAN ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-39 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 33-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,21,23-32 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 14. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 22 and 33-36 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

Response to Amendment

The amendments to the specification and title are acknowledged and accepted.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: element 96. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: elements 512, 310', 338', and 462. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 20, 25-29, 31, 32, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Wyzgala et al. in US Patent No. 6,096,054.

Regarding claim 20, Wyzgala et al. disclose an intraluminal material removal device (generally 200) having a rotatable cutter assembly (such as 226 and associated elements) in communication with a drive shaft (such as 24) for receiving rotational torque from the drive shaft, the cutter assembly (such as 226, etc.) having an adjustable diameter cutter having a plurality of cutter blades (226), wherein the adjustable cutter has a first diameter when rotated in a first direction and a second diameter when rotated in a second direction opposite the first, as recited in column 11 and seen in figure 6A, for example.

Regarding claim 25, Wyzgala et al. disclose that as applied to claim 20, as well as, a plurality of cutting blades (226) of the adjustable diameter cutter that are pivotable on axes parallel to a central longitudinal axis of the cutter assembly to expand to the first diameter and to contract to the second diameter, as seen in figure 6A.

Regarding claims 26 and 31, Wyzgala et al. disclose that as applied to claim 25 and 28, as well as, a plurality of stop faces (228, 240) to define the first diameter of the cutting

head when the cutting blades are pivoted (to an expanded position), as recited in column 11, lines 1-40.

Regarding claims 27 and 32, Wyzgala et al. disclose that as applied to claims 25 and 31, as well as, a plurality of support faces (such as a polymeric liner) to contact the cutting blades when the adjustable diameter cutter is in the second diameter/retracted position, as recited in column 10, lines 50-67.

Regarding claim 28, Wyzgala et al. disclose an intraluminal material removal system (generally 200) having a rotatable cutter assembly (such as element 226 and associated components) in operably coupled to a distal end of a drive shaft (24), the cutter assembly having an expandable diameter cutter having a plurality of butting blades (226) pivotable on axes parallel to a central longitudinal axis of the cutter assembly, as recited in column 11 and seen in figure 6A.

Regarding claim 29, Wyzgala et al. disclose that as applied to claim 28, as well as, an expandable diameter cutter that has a design to operated using the principle of differential cutting, given the rotation and vessel damage avoidance.

Regarding claim 37, Wyzgala et al. disclose a method for cutting material from the internal lumen using a material removal system (such as 200) having a cutting assembly with a plurality of blades (226) via expanding the cutter assembly to a first

diameter by rotating the cutter assembly in a first direction; and retracting the cutter assembly to a second diameter by rotating the cutter assembly in a second direction opposite the first direction, as recited in column 11.

Regarding claim 38, Wyzgala et al. disclose that as applied to claim 37, as well as, expanding that is by pivoting of the blades of the cutting assembly on axes parallel to a central longitudinal axis of the cutter assembly to a diameter to defined by stop faces, as recited in column 11 and seen in figure 6A.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 21, 30, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyzgala et al. in US Patent No. 6,096,054 in view of Clement et al. in US Patent No. 5,681,336.

Regarding claim 21, Wyzgala et al. disclose that as applied to claim 20. However, Wyzgala et al. do not explicitly recite a plurality of material removal ports in communication with a lumen, wherein the material removal ports are located between the cutting blades. On the other hand, Clement et al. teach a plurality of material removal ports in communication with a lumen, as recited in claim 5. Therefore, it would

be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Wyzgala et al. to include a plurality of material removal ports in communication with a lumen, wherein the material removal ports are located between the cutting blades, as taught by Clement et al. for the purpose of removing debris.

Regarding claim 30, Wyzgala et al. disclose that as applied to claim 28. However, Wyzgala et al. do not recite an expandable diameter cutter that has a plurality of material removal ports in communication with a lumen, wherein the material removal ports separate the cutting blades. On the other hand, Clement et al. teach an expandable diameter cutter that has a plurality of material removal ports in communication with a lumen, as recited in claim 5. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Wyzgala et al. to include an expandable diameter cutter that has a plurality of material removal ports in communication with a lumen, wherein the material removal ports separate the cutting blades, as taught by Clement et al. for the purpose of removing debris.

Regarding claim 39, Wyzgala et al. disclose that as applied to claim 37. However, Wyzgala et al. do not explicitly recite aspiration to move cut material into ports of the cutter assembly during the expanding of the cutter assembly. On the other hand, Clement et al. teach to move cut material into ports of the cutter assembly in claim 5. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Wyzgala et al. to include aspiration to move cut material into ports of the cutter

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assembly during the expanding of the cutter assembly, as taught by Clement et al. for the purpose of removing debris.

8. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyzgala et al. in US Patent No. 6,096,054 in view of Clement et al. in US Patent No. 5,681,336 and further in view of Wulfman et al. in US Patent No. 5,584,843.

Regarding claim 23, Wyzgala et al. disclose that as applied to claim 20. However, Wyzgala et al. do not explicitly recite a cutter assembly further having a fixed diameter cutter distally positioned from the adjustable cutter, the fixed diameter cutter having a plurality of cutting blades and a plurality of material removal ports in communication with the lumen. On the other hand, Clement et al. teach plurality of material removal ports, as recited in claim 5. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Wyzgala et al. to include a plurality of material ports. Further Wulfman et al. teach multiple fixed diameter ablation devices. Therefore, it would be obvious to further modify the invention of Wyzgala et al to include a fixed diameter cutter distally positioned from the adjustable cutter, the fixed diameter cutter having a plurality of cutting blades and a plurality of material removal ports in communication with the lumen.

Regarding claim 24, Wyzgala et al. as modified discloses that as applied to claim 23, as well as, an adjustable diameter cutter of a fixed diameter cutter that is designed to

operate using the principle of differential cutting given the rotation and avoidance of vessel damage.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2002/0010487; US Patent No. 6,565,588; US Patent No. 6,503,261; US Patent No. 6,416,526; US Patent No. 6,451,037; US Patent No. 4,926,858 and US Patent No. Re. 36,764.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.


Henry Bennett
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